California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Dazé, Board Member
Hank Hough, Board Member
Ken Schell, PharmD, Board Vice-President

REGULATION REPORT

1. Board Action on Regulations – BOARD ACTION REQUIRED

The following pending regulations were noticed on December 22, 2006. The Comment period is over February 5, 2007. The board may take action on the two pending regulations at the January Board meeting, even though the 45-day period has not run, as long as a motion is made to adopt the regulations as noticed and absent any negative comments or substantive changes.

A separate motion is required by the board to act on each regulation.

a. Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation

Recommendation: Adopt Proposed Amendment to 16 CCR 1775.4 - Reschedule of an Office Conference to Contest a Citation and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

Copies of the Notice, language and Initial Statement of Reasons are provided in Attachment 1.

b. Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files

RECOMMENDATION: Adopt Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needles and syringes, pharmacist interns and designated representatives to the regulation.

Copies of the Notice, language and Initial Statement of Reasons are provided in Attachment 2.

To date, no comments have been received.

2. Proposed Regulations for Board Approval – BOARD ACTION REQUIRED

a. Section 100 – Changes without Regultory Effect

At the January 8, 2007 committee meeting, board staff presented two additional Section 100 changes for committee and board approval.

RECOMMENDATION: Approve the amendments to 16 CCR 1715 – Self Assessment Forms and 16 CCR 1793.8.

- **Amend CCR 1715 – Self Assessment Forms**

  This self-assessment form is incorporated by reference. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the forms last revision date.

- **Amend CCR 1793.8**

  This section currently references Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

A copy of the revised language is included in Attachment 3.

b. Proposed Addition to CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

RECOMMENDATION: Approve the addition of 16 CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

A copy of the proposed language is included in Attachment 4.

3. Approved Regulations – FOR INFORMATION ONLY

The Office of Administrative Law recently approved two board rulemaking files.

a. Repeal 16 CCR 1717(e) and add 16 CCR 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

Section 1717(e) was repealed and Section 1713 was added to Title 16 to allow pharmacy patients the ability to use a vending-like machine located near the pharmacy to obtain their refill medication if they choose to do so. This regulation also allows the use of a prescription drop-off box outside the pharmacy as a means to leave a prescription for a pharmacy to later fill. These changes are effective January 26, 2007.

A copy of the exact language is provided in Attachment 5.

b. Amend 16 CCR 1793.7 and add 16 CCR 1798.8 – Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Setting

Section 1793.7 was amended and Section 1798.8 was added to Title 16 to define the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting. This regulation took effect January 5, 2007.

A copy of the exact language is provided in Attachment 6.

4. Pending Regulations

a. Board Adopted Regulations – Pending Administrative Review – FOR INFORMATION ONLY

At the October 2006 board meeting, the board voted to adopt two pending regulation changes.

Repeal of 16 CCR 1717.2 Notice of Electronic Prescription Files

The repeal of Section 1717.2 of the California Code of Regulations removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy. This rulemaking was submitted to the Office of Administrative Law on January 9, 2007.

A copy of the exact language is in Attachment 7.

Adoption of 16 CCR 1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge

The adoption of Section 1784 of the California Code of Regulations establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This rulemaking was submitted to the Department on December 28, 2006.

A copy of the exact language is in Attachment 8.

b. Board Approved Regulations Awaiting Notice – FOR INFORMATION ONLY

Section 100 Changes – Changes without Regulatory Effect

The board previously approved four Section 100 changes. (A Section 100 change is used when a regulation requires changes that are technical rather than substantive.) These proposals are pending.

(1) Proposed Amendment to 16 CCR 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"

In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

(2) Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material

Section 1780 sets minimum standards for drug Wholesalers. Section 1780(b) references the 1990 edition of the United States (USP) Pharmacopeia Standards for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

(3) Proposed Amendment to 16 CCR 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"

In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006.

(4) Proposed Repeal of 16 CCR 1786 – Return of Exemption Certificates

This section is outdated and needs to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law, which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

A copy of the revised language is included in Attachment 9.

<u>Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines – FOR INFORMATION ONLY</u>

(5) In addition to the Section 100 changes listed above, the board also approved amendment to 16 CCR 1760 – Disciplinary Guidelines.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff has additional recommendations for changes that will be presented to the board at the April 2007 board meeting. No action will be taken on this proposal pending the outcome of the April 2007 board meeting.

c. Board Approved Regulation Awaiting Conformance with California Building Standards Rulemaking Process – FOR INFORMATION ONLY

At the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound injectable solutions. This summer, the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. Staff will pursue these changes in the new format this year to secure adoption of these standards into the building code.

d. Board Approved Regulations – Proposed Language to be Developed – FOR INFORMATION ONLY

(1) Process and Criteria to Approve Accreditation Agencies for Pharmacies

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Language will be developed in concert with staff counsel and will be presented at the next Legislation and Regulation Committee meeting.

(2) Proposed Amendment to 16 CCR 1707.3

Currently this regulation only requires a drug utilization review on a new prescription. The recommendation proposed would require this review on all prescriptions, however it would not require consultation on all prescriptions, rather just that a drug utilization review be completed in advance of dispensing the medication.

The committee generally supported this proposal but recommends a discussion at the January 2007 Board Meeting.

A copy of the revised language is included in Attachment 10.

ATTACHMENT 1

16 CCR 1775.4
Notice, language and Initial Statement of Reasons

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 5, 2007.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on January 22, 2007.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 125.9, 148, 685 and 4005 of the Business and Professions Code and Section 56.63 of the Civil Code, and to implement, interpret or make specific Sections 125.9, 148 and 685 of the Business and Professions Code and Section 56.63 of the Civil Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to $5,000 for violations of the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the regulations adopted pursuant thereto.

Business and Professions Code Section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to $5,000 to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice).

Business and Professions Code Section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code Section 4005 authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code Section 4067 authorizes the board to issue a citation with a fine of up to $25,000 per violation for dispensing a dangerous drug or dangerous

device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code Section 4127.4 authorizes the board to issue a citation with a fine of up to $2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code Section 56.36 authorizes the board to issue citations and fines ranging from $5,000 up to $250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

Section 1775.4 details the procedures for contesting a citation. This proposal would allow for a person or entity to request that the informal office conference to contest a citation issued be rescheduled. Such a request could only be made once.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:
The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not affect small businesses. The proposed regulations affect internal board operations and would have no effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy determined that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy
Specific Language

Amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1775.4 (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)
(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference, The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once by submitting a written request at least 2 days in advance of the scheduled office conference.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Note: Authority cited: Sections 129.5, 148 and 4005, Business and Professions Code. Reference: Sections 125.9, 148, 684, 4067, 4127.4 and Business and Professions Code and Section 56.36 of the Civil Code.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Citation and Fine Appeals

Sections Affected: Repeal Amend 1775.4

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

Factual Basis/Rationale

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to $5,000 for violations of the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the regulations adopted pursuant thereto.

Business and Professions Code section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to $5,000 to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice).

Business and Professions Code section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code section 4067 authorizes the board to issue a citation with a fine of up to $25,000 per violation for dispensing a dangerous drug or dangerous device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code section 4127.4 authorizes the board to issue a citation with a fine of up to $2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code section 56.36 authorizes the board to issue citations and fines ranging from $5,000 up to $250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

Section 1774.5 of the California Code of Regulations allows a person or entity served with a citation to contest the citation. Such individuals can either request a hearing before an administrative law judge pursuant to the Administrative Procedures Act, request an informal office conference conducted by the board's executive officer or his or her designee, or both. This section details many of the procedures for the informal office conference, including necessary timeframes, but does not allow for an office conference to be rescheduled. This proposal would allow for a person or entity to reschedule the office conference one time.

Underlying Data

The board issued 774 citations in FY 2005/2006.
The board scheduled 177 informal office conferences during FY 2005/2006, 48 individuals requested to postpone the appeal conference and an additional seven persons or entities failed to appear at the scheduled office conference.

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to repealing the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the repeal of the regulation.

ATTACHMENT 2

16 CCR 1706.2
Notice, language and Initial Statement of Reasons

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 5, 2007.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on January 22, 2006.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 4005 and to implement, interpret, and make specific reference to sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to complete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action other states other than the forfeit of an application fee submitted for an application that is deemed abandoned.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business other than the forfeit of an application fee submitted for an application that is deemed abandoned

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy
Specific Language

Amend Section 1706.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy~~,~~ wholesaler, out-of-state distributor, ~~or~~ clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

(e) An applicant for a pharmacist intern license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Abandonment of Application Files

Sections Affected: Amend 1706.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes amending Section 1706.2 of the California Code of Regulations to add applicants for veterinary food-animal drug retailers, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation.

Discussion: In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy and sterile injectable compounding pharmacy to the regulation and delete the terms manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change will add applications for licenses to operate veterinary food-animal drug retailers, sale or dispense hypodermic needles and syringes, serve as a pharmacist intern or designated representative to the regulation.

Factual Basis/Rationale

Currently there is no provision in pharmacy law that defines when an application for a license to operate a veterinary food-animal drug retailer, sale or dispense hypodermic needles and syringes, serve as a pharmacist intern or designated representative. This proposal will make consistent the conditions under which these applications may be abandoned.

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

ATTACHMENT 3

16 CCR 1715
16 CCR 1793.8
Language

Board of Pharmacy
2007 Proposed Section 100 Language

Amend Section 1715 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.
(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new pharmacy permit has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
(c) The components of this assessment shall be on Form 17M-13 (Rev ~~1/05~~ 3/07) entitled "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev ~~1/05~~ 3/07) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4305, 4330, 4332 and 4333, Business and Professions Code.

Amend Section 1793.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in ~~4052~~ 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Section 4005 and 4115, Business and Professions Code.
Reference: Section 4005 and 4115 Business and Professions Code.

ATTACHMENT 4

16 CCR 1785
Language

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new veterinary food-animal drug retailer permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.
(c) The components of this assessment shall be on Form 17M-?? (rev. ??/??/2007) entitled "Veterinary Food-Animal Drug Retailer of Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.
(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

ATTACHMENT 5

16 CCR 1717(e) & 16 CCR 1713 Language

Order of Adoption

Board of Pharmacy
California Code of Regulations
Change to Title 16, Division 17

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
(6) The device is located adjacent to the secure pharmacy area.
(7) The device is secure from access and removal by unauthorized individuals.
(8) The pharmacy is responsible for the prescription medications stored in the device.
(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Virginia Herold
Interim Executive Officer

12/22/06
Date

ATTACHMENT 6

16 CCR 1793.7 &
16 CCR 1798.3
Language

Order of Adoption

Board of Pharmacy
California Code of Regulations
Change to Title 16, Division 17

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.
(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.
(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.
(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:
(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.
(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.
(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.
(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Section 4005 and 4115, Business and Professions Code.
Reference: Section 4005 and 4115 Business and Professions Code.

Virginia Herold
Interim Executive Officer

12/1/06
Date

ATTACHMENT 7

16 CCR 1717.2

Language

Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1717.2. Notice of Electronic Prescription Files.**~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~_____ _____~~
~~(date) (signature of patient)~~

~~_____ _____~~
~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

ATTACHMENT 8

16 CCR 1784
Language

Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (rev. 8/14/2006) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B & P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

☐ sole owner ☐ partnership ☐ corporation ☐ LLC

☐ non- licensed owner ☐ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Daily_____Sat_____ Sun_____ 24 Hours ☐

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH#_____Exp. Date _____

2. _____ DR#/RPH#_____Exp. Date _____

3. _____ DR#/RPH#_____Exp. Date _____

4. _____ DR#/RPH#_____Exp. Date _____

5. _____ DR#/RPH#_____Exp. Date _____

6. _____ DR#/RPH#_____Exp. Date _____

7. _____ DR#/RPH#_____Exp. Date _____

8. _____ DR#/RPH#_____Exp. Date _____

9. _____ DR#/RPH#_____Exp. Date _____

10_____ DR#/RPH#_____Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B & P 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note:: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B & P 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ Are clean and orderly
☐ ☐ ☐ Are well ventilated
☐ ☐ ☐ Are free from rodents and insects
☐ ☐ ☐ Are adequately lit
☐ ☐ ☐ Have plumbing in good repair
☐ ☐ ☐ Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B & P 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes	No	N/A	
☐	☐	☐	The owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory. (B & P 4081[b])
☐	☐	☐	Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B & P 4160[d])
☐	☐	☐	The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P 4305.5[a])
☐	☐	☐	The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.
☐	☐	☐	The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B & P 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes	No	N/A	
☐	☐	☐	If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B & P 4100, 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes	No	N/A	
☐	☐	☐	Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B & P 4163[b], 4169)

Yes No N/A

☐ ☐ ☐ If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B & P 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ Is all drug stock open for inspection during regular business hours? (B & P 4081[a])

☐ ☐ ☐ Are all drugs you order maintained in a secure manner at your licensed wholesale premises?. You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B & P 4167)

☐ ☐ ☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B & P 4342[a])

Yes No N/A

☐ ☐ ☐ Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

☐ ☐ ☐ When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (B & P 4059.5[a] [b][d], B & P 4169)

_____

_____

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ Are drugs only furnished by your business to an authorized person? (B & P 4163[a]) Note: An authorized person can be a business or natural person.

Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ your business is a "reverse distributor"?

☐ ☐ ☐ the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B & P 4126.5[a])

Are all drugs that are purchased from another business or are sold, traded or transferred by your business:

☐ ☐ ☐ completed with a business licensed with this board as a wholesaler or pharmacy?

☐ ☐ ☐ free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ beyond their use date (expired drugs)? (B & P 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B & P 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2007, an electronic pedigree must accompany all drugs (B & P 4163), even those for which your business is an authorized distributor.

☐ ☐ ☐ If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P 4380)

☐ ☐ ☐ Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B & P 4341, B & P 651, CCR 1766)

☐ ☐ ☐ Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B & P 650)

_____

_____

Yes No N/A

☐ ☐ ☐ Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B & P 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

Yes No N/A

☐ ☐ ☐ Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B & P 4166[a])

List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B & P 4059.5[a])

☐ ☐ ☐ Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B & P 4059[d])

☐ ☐ ☐ All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B & P 4059.5[c])

☐ ☐ ☐ If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B & P 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. Controlled Substances

Yes No N/A

☐ ☐ ☐ Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

Yes	No	N/A	
☐	☐	☐	Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])
☐	☐	☐	Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
☐	☐	☐	Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])
☐	☐	☐	Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])
☐	☐	☐	Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.07)

List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes	No	N/A	
☐	☐	☐	Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
☐	☐	☐	If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
☐	☐	☐	Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
☐	☐	☐	If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
☐	☐	☐	If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes	No	N/A	
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances.(CFR 1301.74[f])
☐	☐	☐	If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[f])
☐	☐	☐	Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)
☐	☐	☐	When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.09 [b])
☐	☐	☐	If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.11)
☐	☐	☐	When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.05[b])
☐	☐	☐	For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.09[e])
☐	☐	☐	Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances?
☐	☐	☐	Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.12)
☐	☐	☐	Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the

making? (B & P 4081, CCR 1718, CFR 1305.09[d], 1305.13[a] [b], and H & S 11252, 11253, 1304.03)

Yes No N/A

☐ ☐ ☐ Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

Does your business always comply with the following requirements:

Yes No N/A

☐ ☐ ☐ Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)

☐ ☐ ☐ Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes No N/A

☐ ☐ ☐ Receipt of drugs?
☐ ☐ ☐ Security of drugs?
☐ ☐ ☐ Storage of drugs? (including maintaining records to document proper storage)
☐ ☐ ☐ Inventory of drugs? (including correcting inaccuracies in inventories)
☐ ☐ ☐ Distributing drugs?
☐ ☐ ☐ Identifying, recording and reporting theft or losses?
☐ ☐ ☐ Correcting errors?
Physically quarantining and separating:
☐ ☐ ☐ returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
☐ ☐ ☐ drugs that have been partially used?
☐ ☐ ☐ drugs where the outer or secondary seals on the container have been broken?

Yes No N/A

☐ ☐ ☐ drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

☐ ☐ ☐ drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes No N/A

☐ ☐ ☐ Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B & P 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B & P 4059[d])

☐ ☐ ☐ Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the

prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B & P 4059[b])

☐ ☐ ☐ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B & P 4081[a], 4105[c], 4081, 4332, 4059.5[a])

☐ ☐ ☐ Are all purchase and sales records retained in a readily retrievable form? (B & P 4105[a])

☐ ☐ ☐ Is a current accurate inventory maintained for all dangerous drugs? (B & P 4081, 4332, 1718)

☐ ☐ ☐ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B & P 4105[b])

☐ ☐ ☐ Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

Yes No N/A

☐ ☐ ☐ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

☐ ☐ ☐ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B & P 4162[a][4]):

_____

_____

Yes No N/A

☐ ☐ ☐ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B & P 4083)

☐ ☐ ☐ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B & P 4315[e])

☐ ☐ ☐ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B & P 4101[b], 4305.5[c].

☐ ☐ ☐ The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B & P 4305.5[a])

Yes No N/A

☐ ☐ ☐ The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

☐ ☐ ☐ Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B & P 4201[i], CCR 1709[b])

☐ ☐ ☐ When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B & P 4164[a])

☐ ☐ ☐ Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
2. identify purchases of any dangerous drugs at preferential or contract prices
3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B & P 4164[b])

☐ ☐ ☐ I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B & P 4201[g])

☐ ☐ ☐ The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

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17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B & P 4107, CFR 1305.11[a], B & P 4059.5[e])

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

Legal References

All references to California Business & Professions Code (B & P) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws http://www.dhs.ca.gov/fdb/PDF/Sherman%202006.PDF

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (http://www.deadiversion.usdoj.gov/21cfr/index.html).

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
http://www.mbc.ca.gov

Dental Board of California
1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
http://www.ombc.ca.gov

Physician Assistant Committee
1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
http://www.physicianassistant.ca.gov

Board of Podiatric Medicine
1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960
(Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
Registration: (888) 304-3251 or
(415) 436-7900
Theft Reports or Diversion: (415) 436-7854

DEA - Sacramento
4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100
or (916) 480-7250

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000
or (909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (408) 291-7620
or (408) 291-2631

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

ATTACHMENT 9

Section 100 Changes

Language

Board of Pharmacy
Specific Language

CCR 1709.1 Designation of Pharmacist-in-Charge

Amend Section 1709.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

CCR 1780. Minimum Standards for Wholesalers.

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:

(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair.

Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990~~ 2005, 28th ~~22nd~~ Revision).

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990~~ 2005, 28th ~~22nd~~ Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

CCR 1780.1.Minimum Standards for Veterinary Food-Animal Drug Retailers

Amend Section 1780 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

g. Refilling A Veterinarian's Prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer

(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)

(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the qualifying

experience earned by an applicant for registration must do so under penalty of perjury.

Note: Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

CCR 1781. Exemption Certificate

Amend Section 1781 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

A registered pharmacist, or ~~an exemptee~~ designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.

CCR 1786. Exemptions.

Repeal Section 1786 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~(a) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4054, leaves the employ of a supplier, said supplier shall immediately return the certificate of exemption to the board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4051, 4053 and 4054, Business and Professions Code.~~

ATTACHMENT 10

16 CCR 1707.3
Language

Board of Pharmacy
Specific Language

Amend Section 1707.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1707.3. Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery.

~~Prior to consultation as set forth in section 1707.2, a~~ A pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

Note: Authority cited: Section 4005 Business and Professions Code
Reference: Section 4005 Business and Professions Code